IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of:	David MORTON et al.	
Serial No.:	10/571,146	Confirmation No. 3651
Filed:	Herewith as national phase of International Application No. PCT/GB2004/003996, filed September 15, 2004	
For:	**DRY POWDER COMPOSITION COMPRISING CO-JET MILLED PARTICLES FOR PULMONARY INHALATION**	

MAIL STOP: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

December 8, 2011

RESPONSE TO FINAL OFFICE ACTION

Sir:

In response to the final Office Action of June 14, 2011, Applicants submit the following:

Amendments to Claims begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (currently amended) A method for making a pharmaceutical composition comprising carrier particles and composite active particles for pulmonary inhalation, the method comprising the step of jet milling active particles in the presence of particles of additive material so that the additive material coats the active particles to form composite active particles, wherein the additive material is selected from the group consisting of: an amino acid, a metal stearate and a phospholipid, the method further comprising blending the carrier particles with the composite active particles.

Claim 2. (cancelled)

Claim 3. (previously presented) A method as claimed in claim 1, wherein the additive material is selected from the group consisting of: leucine, isoleucine, lysine, valine, methionine, phenylalanine, and a combination of any of the foregoing.

Claim 4. (previously presented) A method as claimed in claim 3, wherein the additive material comprises one of the following: leucine and L-leucine.

Claim 5. (previously presented) A method as claimed in claim 1, wherein the additive material comprises magnesium stearate.

Claim 6. (previously presented) A method as claimed in claim 1, wherein the additive material comprises lecithin.

Claim 7. (previously presented) A method as claimed in claim 1, wherein the step of jet milling is carried out at an inlet pressure of between 0.1 and 3 bar.

Claim 8. (previously presented) A method as claimed in claim 1, wherein the step of jet milling is carried out at an inlet pressure of between 3 and 12 bar.

Claim 9. (previously presented) A method as claimed in claim 1, wherein at least 90% by volume of the active particles are less than 20μm in diameter prior to the step of jet milling.

Claim 10. (previously presented) A method as claimed in claim 1, wherein at least 90% by volume of the additive particles are less than 20μm in diameter prior to the step of jet milling.

Claim 11. (previously presented) A method as claimed in claim 1, wherein the step of jet milling is carried out at temperatures below room temperature.

Claim 12. (previously presented) A method as claimed in claim 11, wherein the step of jet milling is carried out at a temperature below 10°C.

Claim 13. (previously presented) A method as claimed in claim 1, wherein the step of jet milling further comprises jet milling carrier particles with the active particles and the particles of additive material.

Claim 14. (original) A method as claimed in claim 13, wherein the carrier particles have a particle size of at least 20μm.

Claim 15. (previously presented) A method as claimed in claim 13, wherein the carrier particles have a particle size of less than 30μm.

Claim 16. (currently amended) A pharmaceutical composition comprising composite active particles prepared in accordance with the method as claimed in claim 1, blended with carrier particles.

Claim 17. (previously presented) The pharmaceutical composition of claim 16, wherein said composition is for pulmonary inhalation.

Claim 18. (cancelled)

Claim 19. (previously presented) The pharmaceutical composition of claim 1, wherein the coating is a discontinuous coating.

Claim 20. (previously presented) The pharmaceutical composition of claim 1, wherein the coating of additive material is not more than 1μm in thickness.

Claim 21. (previously presented) The pharmaceutical composition of claim 16, wherein said composite active particles have an MMAD of not more than 10μm.

Claim 22. (previously presented) The pharmaceutical composition of claim 21, wherein said composite active particles have an MMAD of not more than 5μm.

Claim 23. (previously presented) The pharmaceutical composition of claim 16, wherein at least 90% by weight of the composite active particles have a diameter of not more than 10μm.

Claim 24. (previously presented) The pharmaceutical composition of claim 23, wherein at least 90% by weight of the particles have a diameter of not more than 5μm.

Claims 25-26 (cancelled)

Claim 27. (previously presented) A composition as claimed in claim 16, wherein the composition is a dry powder composition.

Claim 28. (cancelled) ~~A composition as claimed in claim 27, wherein the composition further comprises carrier particles.~~

Claim 29. (previously presented) A composition as claimed in claim 16, wherein the composition has a FPF(ED) of at least 70%.

Claim 30. (previously presented) A composition as claimed in claim 29, wherein the FPF(ED) is at least 80%.

Claim 31. (previously presented) A composition as claimed in claim 16, wherein the composition has a FPF(MD) of at least 60%.

Claim 32. (previously presented) A composition as claimed in claim 29, wherein the FPF(MD) is at least 70%.

Claim 33. (previously presented) A dry powder inhaler containing a composition as claimed in claim 16.

Claim 34. (cancelled)

Claim 35. (previously presented) A method as claims in claim 1, wherein the step of jet milling active particles is carried out in the presence of particles of additive material and one of the following: air, compressible gas and fluid.

Claim 36. (previously presented) A method according to claim 11, wherein the step of jet milling is carried out at a temperature below 0 ℃.

Claim 37. (previously presented) A method as claimed in claim 13, wherein the carrier particles have a particle size of less than 20μm.

Claim 38. (previously presented) A method as claimed in claim 13, wherein the carrier particles have a particle size of less than 10μm.

Claim 39. (previously presented) A pharmaceutical composition as claimed in claim 21, wherein said composite active particles have an MMAD of not more than 1μm.

Claim 40. (previously presented) A pharmaceutical composition as claimed in claim 23, wherein at least 90% by weight of the particles have a diameter of not more than 1μm.

Claim 41. (previously presented) A composition as claimed in claim 29, wherein the FPF(ED) is at least 90%.

Claim 42. (previously presented) A composition as claimed in claim 29, wherein the FPF(ED) is at least 85%.

REMARKS

Claims 1, 3-17, 19-24, 27, 29-33, and 35-42 are pending in this application. Claim 28 has been canceled, without prejudice.

Claim 1 has been amended to specify that the pharmaceutical composition comprises carrier particles and that the carrier particles are blended with the composite active particles. Support for this amendment is found throughout the specification, including claim 28 as filed. Claim 28 has therefore been canceled. Claim 16 also has been amended to specify that the composite active particles are blended with carrier particles.

It is respectfully submitted that no new matter has been added by virtue of these amendments.

Double patenting rejections

Claims 1, 5-8, 11-12, 16-20, 23-24, 27, and 35 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 16-19, and 21- 22 of U.S. Patent No. 7,736,670.

Independent claim 1 of the present application has been amended to read as follows:

> A method for making a pharmaceutical composition comprising carrier particles and composite active particles for pulmonary inhalation, the method comprising the step of jet milling active particles in the presence of particles of additive material so that the additive material coats the active particles to form composite active particles, wherein the additive material is selected from the group consisting of: an amino acid, a metal stearate and a phospholipid, the method further comprising blending the carrier particles with the composite active particles.

Independent Claim 1 has been amended to specify that the pharmaceutical composition comprises carrier particles and that the carrier particles are blended with the composite active particles. The remainder of the claims depend from claim 1. Therefore, the rejection has been overcome.

Applicants respectfully request withdrawal of this rejection.

Claims 1-2, 5-8, 11-12, 16-24, 27, 35-36, and 39-40 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20, 33-35, 37, 39, 42-43, and 59-61 of copending Application No. 10/433,185 (now U.S. patent No. 8,048,451 issued November 1, 2011).

Independent Claim 1 has been amended to specify that the pharmaceutical composition comprises carrier particles and that the carrier particles are blended with the composite active particles. The remainder of the claims depend from claim 1. Therefore, the rejection has been overcome.

Applicants respectfully request withdrawal of this rejection.

Claims 1-2, 5, 7-8, 11-12, 16-17, 21-22, 27, 29-33, 35, and 41-42 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/552,326.

Independent Claim 1 has been amended to specify that the pharmaceutical composition comprises carrier particles and that the carrier particles are blended with the composite active particles. The remainder of the claims depend from claim 1. Therefore, the rejection has been overcome.

Applicants respectfully request withdrawal of this rejection.

Claims 1, 7-8, 11-16, 28, and 35-38 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-9, and 26 of copending Application No. 11/791,385.

Independent Claim 1 has been amended to specify that the pharmaceutical composition comprises carrier particles and that the carrier particles are blended with the composite active particles. It should be noted that the carrier particles are added to the composite active particles by blending, a step which does not result in the additive material becoming fused to the surface of the carrier particles.

The remainder of the claims depend from claim 1. Therefore, the rejection has been overcome.

Applicants respectfully request withdrawal of this rejection.

Claims 1-12, 16-24, 29-32, 35-36, and 39-42 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6, 12, 15-22, 26, 30, and 39-40 of copending Application No. 11/791,670.

Independent Claim 1 has been amended to specify that the pharmaceutical composition comprises carrier particles and that the carrier particles are blended with the composite active particles. The remainder of the claims depend from claim 1. Therefore, the rejection has been overcome.

Applicants respectfully request withdrawal of this rejection.

Claims 16-18, 21-24, and 27-33 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35, 38, 41-43, and 45 of copending Application No. 12/767,530.

Independent Claim 1 has been amended to specify that the pharmaceutical composition comprises carrier particles and that the carrier particles are blended with the composite active particles. The remainder of the claims depend from claim 1. Claims 43 and 44 of this copending application do recite carrier particles. For purposes of expediting prosecution in the present

application, Applicants are concurrently filing an Amendment in copending Application No. 12/767,530 canceling claims 43 and 44. Therefore, the rejection has been overcome.

Applicants therefore respectfully request withdrawal of this rejection.

Applicant is canceling claims 39-41 of U.S. Application No. 13,269,025 and claim 19 of U.S. Application No. 10/433,135 to expedite prosecution in the present application. These claims recite the use of carrier particles. Amendments in each of these applications are being filed for this purpose concurrently with the filing of the present Response After Final Office Action.

CONCLUSION

Reconsideration of the present application is requested. This Response is being submitted in response to the Office Action dated June 14, 2011 in the above-identified application. Concurrently with this Response, Applicant submits a petition for a three-month extension of time for filing a response, along with the requisite fee. If it is determined that any additional fee is due in connection with this filing, the Commissioner is authorized to charge said fees to Deposit Account No. 50-0552.

If the Examiner has any questions or concerns regarding this amendment, the Examiner is respectfully requested to contact either Cliff Davidson or Cary Kappel of our firm at the number set forth below. The undersigned reminds the Examiner that she will be out of the office until after the final due date for this response and will not receive any phone messages.

An early and favorable action on the merits is earnestly requested.

Respectfully Submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: / Leslye Davidson/
Leslye Davidson
Reg. No. 38,854

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, NY 10018
(212) 736-1940